

In re application of: Jeffrey Schlom; Judith Kantor; Donald Kufe; Dennis Panicali,
and Linda Gritz
Application No.: 10/057,136 Group No.: 1632
Filed: 01/25/2002 Examiner: Ram R. Shukla
For: RECOMBINANT POX VIRUS FOR IMMUNIZATION AGAINST MUC1
TUMOR-ASSOCIATED ANTIGEN

CLAIMS

Claims 1 – 22 (cancelled)

- Claim 23 (New) A recombinant pox virus comprising a nucleic acid sequence encoding an immunogenic MUC1 fragment comprising approximately 5 to 25 MUC1 tandem repeat units, wherein said nucleic acid sequence is altered from the native tandem repeat pattern by using alternative codons to reduce homology between the repeats.
- Claim 24 (New) The recombinant pox virus of claim 1, wherein the immunogenic MUC1 fragment comprises approximately 7 to 15 MUC1 tandem repeat units.
- Claim 25 (New) The recombinant pox virus of claim 2, wherein the immunogenic MUC1 fragment comprises 10 MUC1 tandem repeat units.
- Claim 26 (New) The recombinant pox virus of claim 1, wherein the pox virus is selected from the group consisting of orthopox, suipox and avipox.
- Claim 27 (New) A pharmaceutical composition comprising:
- (a) a recombinant pox virus comprising a nucleic acid sequence encoding an immunogenic MUC1 fragment comprising approximately 5 to 25 MUC1 tandem repeat units, wherein said nucleic acid sequence is altered from the native tandem repeat pattern by using alternative codons to reduce homology between the repeats, and an immunomodulator.
- Claim 28 (New) The pharmaceutical composition of claim 5, wherein the immunomodulator is selected from the group consisting of T-cell co-stimulatory factors and cytokines.
- Claim 29 (New) The pharmaceutical composition of claim 6, wherein the cytokine is an interleukin.
- Claim 30 (New) The pharmaceutical composition of claim 5, wherein the immunomodulator is both a T-cell co-stimulatory factor and a cytokine.
- Claim 31 (New) The recombinant pox virus of claim 5, wherein the pox virus is selected from the group consisting of orthopox, suipox and avipox.
- Claim 32 (New) The pharmaceutical composition of claim 5, wherein the immunomodulator is encoded by a nucleic acid sequence on a separate pox virus from said recombinant pox virus comprising the nucleic acid sequence encoding said immunogenic MUC1 fragment.

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- Claim 33 (New) The pharmaceutical composition of claim 5, wherein the immunomodulator and the immunogenic MUC fragment are both encoded by nucleic acid sequences located on a single pox virus.
- Claim 34 (New) The pharmaceutical composition of claim 5, wherein said MUC1 fragment comprises about 7 to 15 tandem repeat units.
- Claim 35 (New) A method of generating an immune response in a mammal having a MUC1-expressing tumor comprising:
- (a) administering to the mammal the pox virus of claim 1; and
 - (b) administering a second amount of pox virus wherein the pox virus is selected from the group consisting of orthopox, suipox and avipox.
- Claim 36 (New) The method of claim 13 wherein said boosting is administered by using an effective amount of second recombinant pox virus from a different viral genus from said pox virus of claim 1.
- Claim 37 (New) The method of claim 13, wherein said mammal is further administered an immunomodulator.
- Claim 38 (New) The recombinant pox virus of claim 1 which is rV-MUC1.
- Claim 39 (New) The method of claim 13 wherein the boosting comprises an effective amount of MUC1 administered as a MUC1 peptide or as a nucleic acid sequence that encodes said MUC peptide.
- Claim 40 (New) A method of inhibiting or killing MUC1 positive tumor cells comprising:
- (a) generating MUC1 specific cytotoxic T-lymphocytes (CTLs) by stimulating harvested lymphocytes in vitro by adding an effective amount of a MUC1 specific antigen to the lymphocytes, alone or in combination with one or more cytokines, to generate said CTLs; and
 - (b) administering the CTLs alone or in combination with a immunomodulator into a mammal in an amount sufficient to inhibit or kill the MUC1 positive tumor cells.
- Claim 41 (New) A method for generating an immune response in a mammal that contains a MUC1-expressing tumor comprising administering to said mammal at least one pox virus of claim 4.